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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/821,828

04/09/2004

Hector F. DeLuca

1256-00949

1399

26753

7590

04/11/2008

ANDRUS, SCEALES, STARKE & SAWALL, LLP
100 EAST WISCONSIN AVENUE, SUITE 1100
MILWAUKEE, WI 53202

EXAMINER

BADIO, BARBARA P

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/821,828	Applicant(s) DELUCA ET AL.	
	Examiner Barbara P. Badio, Ph.D.	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 22-71 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 22-71 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Final Office Action on the Merits

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

2. The rejection of claims 55 and 59-63 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is withdrawn.

3. The rejection of claims 2-11 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn.

4. The rejection of claims 18 and 20 under 35 U.S.C. 112, second paragraph, as being indefinite is made moot by the cancellation of the instant claims.

Double Patenting

5. The rejection of claims 1-17 and 22-71 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of U.S. Patent Nos. 5,843,928; 6,392,071; 6,440,953; 6,482,812; 6,537,981; 6,696,431; 6,774,251; 6,806,262; 6,894,037; 6,992,074; 7,053,075; 7,115,594; 7,208,484; 7,214,670; 6,214,671; 7,232,810; 7,241,747; 7,241,909 and 7,244,719 in view of Bishop et al. (US 5,972,917) or (Deluca et al., WO 96/16035) is maintained.

Applicant argues the compounds of Bishop (a) are not 19-nor analogs and are not 2-alkylidene analogs as presently claimed, (b) are characterized by low intestinal calcium transport resulting in reduced or no hypercalcemia as compared to known active vitamin D compounds and the presently claimed compounds. Applicant also argues DeLuca teaches vitamin D analogs where hydrogen and methyl at the 18-position are not equivalent with respect to biological activity and reference is made to data shown in Figures 1 and 2 of the cited reference. Applicant's argument was considered but not persuasive for the following reasons.

First, it is noted that the genus taught by Bishop is inclusive of 19-nor compounds (see especially col. 5, lines 60-64).

Applicant argues the references do not teach an equivalent in biological activity with hydrogen and methyl at the 18-position. The issue is whether the 18-nor compounds of **5,843,928; 6,392,071; 6,440,953; 6,482,812; 6,537,981; 6,696,431; 6,774,251; 6,806,262; 6,894,037; 6,992,074; 7,053,075; 7,115,594; 7,208,484; 7,214,670; 6,214,671; 7,232,810; 7,241,747; 7,241,909 and 7,244,719** would have been obvious to the skilled artisan based on the teachings of the prior art and the level of skill of the ordinary artisan in the art at the time of the present invention. As discussed in the previous Office Action, the prior art teaches both 18-methyl and 18-nor vitamin D compounds are useful in treating similar diseases such as psoriasis, osteoporosis, multiple sclerosis, etc. (see DeLuca and Bishop). Therefore, the 18-nor compounds of **5,843,928; 6,392,071; 6,440,953; 6,482,812; 6,537,981; 6,696,431; 6,774,251; 6,806,262; 6,894,037; 6,992,074; 7,053,075; 7,115,594; 7,208,484;**

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7,214,670; 6,214,671; 7,232,810; 7,241,747; 7,241,909 and 7,244,719 are rendered obvious because the skilled artisan would have the reasonable expectation that said compounds would also be useful in treating diseases such as psoriasis, osteoporosis, multiple sclerosis, etc.

Additionally, as shown by both references, i.e., Bishop and DeLuca, and argued by applicant, the ability of vitamin D compounds to affect calcium transport and cell differentiation changes with the presence of hydrogen and/or methyl at the 18-position. As taught by DeLuca, the skilled artisan would have the reasonable expectation that the corresponding 18,19-nor compounds of **5,843,928; 6,392,071; 6,440,953; 6,482,812; 6,537,981; 6,696,431; 6,774,251; 6,806,262; 6,894,037; 6,992,074; 7,053,075; 7,115,594; 7,208,484; 7,214,670; 6,214,671; 7,232,810; 7,241,747; 7,241,909 and 7,244,719** would be useful as known in the art for vitamin D compounds but would be characterized by high cell differentiation activity and marked intestinal calcium transport activity as taught by DeLuca.

For these reasons and those given in the previous Office Action, the rejection of claims 1-17 and 22-71 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of U.S. Patent Nos. 5,843,928; 6,392,071; 6,440,953; 6,482,812; 6,537,981; 6,696,431; 6,774,251; 6,806,262; 6,894,037; 6,992,074; 7,053,075; 7,115,594; 7,208,484; 7,214,670; 6,214,671; 7,232,810; 7,241,747; 7,241,909 and 7,244,719 in view of Bishop et al. (US 5,972,917) or (DeLuca et al., WO 96/16035) is maintained.

6. The rejection of claims 18-21 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of U.S. Patent Nos. 5,843,928; 6,392,071; 6,440,953; 6,482,812; 6,537,981; 6,696,431; 6,774,251; 6,806,262; 6,894,037; 6,992,074; 7,053,075; 7,115,594; 7,208,484; 7,214,670; 6,214,671; 7,232,810; 7,241,747; 7,241,909 and 7,244,719 in view of Bishop et al. (US 5,972,917) or (Deluca et al., WO 96/16035) is made moot by the cancellation of the instant claims.

7. The rejection of claims 1, 22, 28-32, 34-38, 40-45, 47-53, 55-62 and 64-70 on the ground of nonstatutory obviousness-type double patenting over claims of US Patent No. 7,238,681 is withdrawn.

The filing of a terminal disclaimer is noted.

8. The provisional rejection of claims 1-17 and 22-71 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of copending Application Nos. 10/997,698 and 11/351,874 in view of Bishop et al. (US 5,972,917) or (Deluca et al., WO 96/16035) is maintained.

Applicant's argument and the examiner's response are as discussed above in #5.

For these reasons and those given in the previous Office Action, the provisional rejection of claims 1-17 and 22-71 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of copending Application Nos.

10/997,698 and 11/351,874 in view of Bishop et al. (US 5,972,917) or (Deluca et al., WO 96/16035) is maintained.

9. The provisional rejection of claims 1-17 and 22-71 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of copending Application Nos. 10/530,903 and 10/544,163 in view of Bishop et al. (US 5,972,917) or (Deluca et al., WO 96/16035) is withdrawn.

10. The provisional rejection of claims 18-21 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of copending Application Nos. 10/530,903; 10/544,163; 10/997,698 and 11/351,874 in view of Bishop et al. (US 5,972,917) or (Deluca et al., WO 96/16035) is made moot by the cancellation of the instant claims.

Claim Rejections - 35 USC § 103

11. The rejection of claims 18-21 under 35 U.S.C. 103(a) over Deluca et al. (WO 96/16035) is made moot by the cancellation of the instant claims.

Conclusion

12. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Telephone Inquiry

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Barbara P. Badio, Ph.D./
Primary Examiner, Art Unit 1612